

**REMARKS**

Claims 1-19 and 21 are currently pending in this application. Applicants have cancelled claim 20 without prejudice and added claims 22 and 23. Reconsideration is respectfully requested in light of the above claim amendments and the following remarks.

In the most recent Office action, dated July 31, 2006, the Examiner rejected claims 1, 2, 5, 6, 9, 12, and 19 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 5,925,073 to Chastain et al. and claims 4, 11, 14 and 18 under 35 U.S.C. § 102(e) as anticipated by or in the alternative under 35 U.S.C. § 103(a) as obvious over Chastain et al. The Examiner further rejected claims 1, 2, 5, 6, 9, 12, 19 and 21 under 35 U.S.C. § 103(a) as being unpatentable over Chastain in view of U.S. Patent Number 6,430,449 to Hsu et al. The Examiner rejected claims 4, 11, 14 and 18 under 35 U.S.C. § 103(a) as obvious over Chastain et al. or in the alternative as obvious over Chastain et al. in view of Hsu et al. and claims 3, 7, 8 and 14-17 as obvious over Chastain et al.

On August 26, 2004 Applicants submitted a rule 1.131 declaration from each of the co-inventors of the subject matter claimed in the present application swearing behind Hsu et al. and effectively Chastain et al. In addition, in an amendment filed June 5, 2006 Applicants submitted the billing records of Applicants' patent firm Knobbe Martin, Olson & Bear, LLP, (hereinafter KMOB) to further demonstrates Applicants diligence during the critical period in reducing the present application to practice. Included in the billing records were the specific billing records for the attorney, Mark M. Abumeri of KMOB who prepared the application that became the grandparent patent application, serial number 09/196,898, (hereinafter "the '898 application") which is identified as KMOB ref. no. Paceset 064A in the submitted billing records.

As required by MPEP §715.07, the rule 1.131 declarations and accompanying exhibits and the submitted billing records established conception of the claimed invention prior to the effective date of the cited references as well as reasonable diligence from prior to the effective date of the cited references to constructive reduction to practice of the present invention (i.e. the filing of the '898 application).

In Office actions, mailed April 8, 2005 and July 31, 2006 the Examiner held that the declarations filed under 37 CFR 1.131 were ineffective to overcome the cited references. Specifically, the Examiner alleged that there were various periods between exhibits where diligence was not shown. For example, the Examiner notes that between Exhibits C and D of the August declarations, a period of one year elapsed. The Examiner further submits that no diligence is shown for the three and half month period between the time when Applicants received a first draft of the application (Exhibit D, dated July 1, 1998) and a revised draft (Exhibit E, dated October 23, 1998) and for the period of approximately one month after receipt of the revised draft until the application was filed. Applicants disagree

Applicants submit that according to MPEP §715.07(a) and 37 CFR 1.131 the critical period in which diligence must be shown begins just prior to the earliest effective date of the cited references (i.e. Feb. 22, 1998, the day before the filing date of Chastain et al. and March 18, 1998 for Hsu et al.) and ends with the date of a reduction to practice, either actual or constructive, (i.e. the filing of the '898 application on November 20, 1998). Therefore, the one year period between Exhibit C (dated June 27, 1997) and Exhibit D (dated July 1, 1998) is immaterial as to whether Applicants were diligent in reducing the invention to practice for purposes of overcoming the cited references. Rather, Applicants are simply required to demonstrate diligence during the critical period between Feb. 22, 1998, the day before the filing date of Chastain et al. and November 20, 1998 the filing date of the '898 application.

Further, according to MPEP §2138.06 reasonable diligence is all that is required of an attorney when preparing an application for filing and that diligence is established if the attorney worked reasonably hard on the application during the critical period. In addition, courts have recognized that it may not be possible for a patent attorney to begin working on an application at the moment the inventor makes the disclosure, because the attorney may already have a backlog of other cases demanding his attention. The courts have further recognized that it is sufficient if an attorney has a reasonable back log of cases which he takes up in chronological order and carries out expeditiously. *Bey v. Kollonitsch*, 806 F.2d 1024, 231 USPQ 967 (Fed. Cir. 1986).

As argued on pages 7 and 8 of the Amendment filed June 5, 2006, the submitted billing records demonstrate that during the months of January 1998 through April, 1998 (prior to the effective date of Chastain et al. and Hsu et al), KMOB attorneys worked on a large number of earlier Pacesetter patent applications according to the chronological order in which they were received. The submitted billing records also demonstrate that Mr. Abumeri began work on the '898 application (Paceset 064A) when he became available on May 7, 1998 and continued to work on the application until a final draft was sent to Pacesetter on October 23, 1998.

Thus, prior to the effective date of the cited references, KMOB lawyers diligently worked on numerous earlier Pacesetter inventions before beginning work on the '898 application which is clearly sufficient to demonstrate reasonable diligence prior to the effective date of Chastain et al. and Hsu et al. In addition, KMOB lawyers continued to work on a large number of additional Pacesetter applications in parallel with the development of the '898 application during the critical period as demonstrated in the submitted billing records and argued on page 8 of the June 5, 2006 amendment.

The submitted billing records further demonstrate that Mr. Abumeri billed in excess of 160 hours in preparing the '898 application over an extended period of time, demonstrating the complexity and importance of this application. In addition, the billing records demonstrate that during the period between Exhibits D and E cited by the Examiner, Mr. Abumeri billed 90 plus hours preparing the revised draft of the '898 application while working on the application part of at least 27 different days. Applicants therefore respectfully submit that Mr. Abumeri worked reasonably hard and was reasonably diligent as required by law in preparing the revised draft of the '898 application during the period between Exhibits D and E.

In addition, Applicants submit herewith (see Exhibit A) a copy of a letter from Pacesetter, Inc. (doing business as St. Jude Medical, CRMD) to Mr. Abumeri dated November 10, 1998 requesting minor revisions to the formal drawings for the revised draft of the '898 application which resulted from the inventors review of the application which was received from Mr. Abumeri on October 23, 1998 (i.e. Exhibit E of the rule 1.131 declarations).

Applicants also submit a copy of a letter from Mr. Abumeri to Pacesetter, Inc. dated November 19, 1998 wherein Mr. Abumeri provided the revised drawings which together with the revised application, were filed with the USPTO on November 20, 1998. Applicants therefore submit that reasonable diligence has therefore been demonstrated during the period between the receipt of the revised application and the filing of the '898 application (i.e. between Exhibit E and the filing date).

Applicants therefore submit that Applicants and their attorneys, as required by law, worked reasonably hard and were reasonably diligent in working on the application that became the '898 application during the critical period. Applicants therefore submit that Chastain et al. and Hsu et al. are not prior art with respect to the claims of the subject application and that the rejections based on Chastain et al and Hsu et al. are moot. Accordingly, Applicants respectfully submit that claims 1-19 and 21 are allowable.

Applicants further submit that for at least the foregoing reasons, neither Chastain et al. nor Hsu et al. are prior art to newly added claim 22 which is therefore allowable. In addition, independent claim 22 recites a lead system comprised in part by a stylet disposed and slidably movable within the lumen of the lead body, wherein when the stylet is partially withdrawn, the s-shaped portion is adapted to form a steerable canted end ... (Underling added for emphasis only). Applicants respectfully submit that neither Chastain et al. nor Hsu et al. disclose or suggest the recited claim elements.

The Examiner argues on page 9 of the most recent Office action that the lead system of Chastain et al. inherently includes a steerable canted end since the stylet can be moved anywhere along the bends providing a steerable canted end when the stylet is partially withdrawn. Applicants respectfully disagree.

Applicants submit that for a lead to provide a steerable canted tip the humps must be adapted to cant the distal tip away from the central axis of the lead when a stylet is not inserted in the lead body as illustrated in FIGS. 3A and 3B of the present application. Such a configuration provides for a variable cant angle as a stylet is partially inserted or withdrawn from the most distal hump of the S-shaped portion, thus providing the steerability.

Applicants submit that the distal tip of the Chastain lead is approximately parallel to the central axis of the lead body and is in no way canted or steerable (see FIG. 1). In addition, on page 3 of the original Office action in this application, dated June 7, 2002, the Examiner admits that Chastain et al. do not teach a lead having a canted tip in rejecting the pending claims as being obvious over Chastain et al. in view U.S. Patent 6,321,123 to Morris or U.S. Patent 5,683,445 to Swoyer.

As demonstrated in Applicants Amendment filed October 4, 2002, the Morris patent, which was filed on March 9, 1999 (after applicants' priority date), is not a proper prior art reference to the subject matter claimed in the present application. Further, Applicants respectfully submit that there is no suggestion or motivation to combine Chastain with Swoyer.

The Swoyer patent discloses a medical electrical lead which is suitably shaped to provide an electrical connection through the coronary sinus to the left atrium. More specifically, Swoyer discloses that the disclosed medical electrical lead includes a pre-bent portion along the lead body which may be readily straightened through use of a stylet and which further includes a pre-bent portion at the electrode tip so that the electrode tip is properly oriented to the coronary sinus upper wall and, thus, with the left atrium inferolateral wall. (Swoyer, col.2, lines 49-64).

Thus the preformed bends of the Swoyer lead are specifically designed and sized for placement in and electrical contact with the left atrium of the heart through the coronary sinus. Swoyer does not in any way disclose or suggest that the distal tip of the lead is steerable or that having such a steerable tip would be beneficial for lead placement.

To the contrary, Swoyer specifically teaches that a guide catheter is used to deliver the Swoyer lead to the desired location within the body so that having a steerable tip would be of no benefit to the Swoyer lead. (Swoyer, FIG. 6, col. 5, lines 25-29).

In addition, as the Examiner noted in the March 9, 1999 the lead of Chastain et al. does not include or contemplate the use of a tip electrode. Further the pacing lead of Chastain et al. is "specifically designed to be routed through the coronary sinus and

into the great cardiac vein or branch vein, traversing the epicardium of the left ventricle.” (Chastain et al., col. 2, lines 42-44).

Thus, Chastain et al. discloses a left ventricular lead with a ring electrode on a distal portion that is oriented approximately parallel to a central axis of the lead. Thus one of skill in the art would not be motivated to incorporate the geometry of the Swoyer lead which is optimized for placement in the coronary sinus for contact with the left atrium into the left ventricular lead of Chastain et al.

Further, there is no teaching or suggestion in Swoyer or Chastain et al. that a distal bend designed to electrically couple a tip electrode to a patient's left atrium would in any way be beneficial in a left ventricular lead having a ring electrode that is not physically coupled to the vein wall (Chastain FIG. 1). In addition, there is no teaching or suggestion in Chastain et al. that the ring electrode of the Chastain et al. lead electrically decouples from the left ventricle post implant or that lead performance would benefit from a canted distal end with a tip electrode.

Moreover, there is no teaching or suggestion in Swoyer et al. or Chastain et al. that the tip of the Swoyer lead creates a steerable canted tip or that such a tip is beneficial when placing a left ventricular lead. Rather, as noted above the lead of Swoyer is placed with a guide catheter.

As such, absent applicants' disclosure, there is no suggestion to combine these references. Accordingly, one of ordinary skill in the art would not be motivated to combine Swoyer with Chastain et al., because those references teach different solutions to different problems.

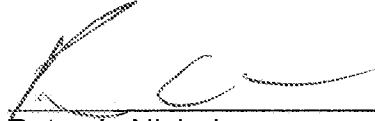
Applicants further submit that the rule 1.132 declaration of David Kistler submitted December 8, 2005 also demonstrates the non-obviousness of the claimed invention. For at least the foregoing reasons, Applicants further submit that newly added claim 22 is also allowable

**PATENT**

In view of the foregoing, it is respectfully submitted that all of the pending claims patentably distinguish over the cited references, and a Notice of Allowance is earnestly solicited.

Respectfully submitted,

10-26-06  
Date

  
\_\_\_\_\_  
Peter A. Nichols  
Reg. No. 47,822  
Attorney for Applicant(s)

Enclosure: Exhibit A

**CUSTOMER NUMBER: 36802**

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November 10, 1998

Mark Abumeri  
KNOBBE MARTENS OLSON & BEAR  
501 West Broadway, Suite 1400  
San Diego, CA 92101

Re: Draft Patent Applications  
A SELF-ANCHORING CORONARY SINUS LEAD  
Your Ref. 064A  
Our Docket Nos. 98P 1021 and 98P 1022 (prev. 97E1010)

Dear Mark:

Enclosed are 5 sheets of the 11 sheets formal drawings you provided for the above-identified patent applications.

Please make minor changes as red-lined:

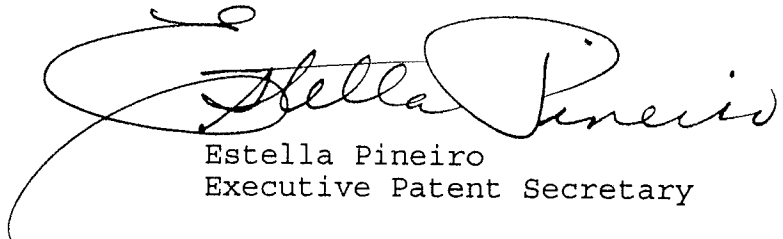
FIG. 3A; FIG. 3D; FIG. 4B; FIG. 4C; FIG. 8; FIG. 9

**EXCEPT FIG. 9:**

The darkened areas (950) should not appear like that. Would you please make correction; and also, designators 912 and 950 are both pointing to the same spot. Could you make it more obvious as to what each designator is?

Please feel free to call if you have any questions.

Very truly yours,



Estella Pineiro  
Executive Patent Secretary

/ep  
Enclosures



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November 19, 1998 7

## VIA FEDERAL EXPRESS

Ms. Estella Pineiro  
Executive Patent Secretary  
PACESETTER, INC.  
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Re: U.S. Patent Application  
Title: A SELF-ANCHORING CORONARY SINUS LEAD  
Our Reference: PACESET.064A  
Your Reference: 98P 1021 - 98P 1022

Dear Estella:

Enclosed are five sheets with the revisions you requested for Figures 3A, 3D, 4B, 4C, 8 and 9, for the above-identified patent application.

If you have any questions, please give me a call.

Sincerely,

*Mark Abumeri*  
Mark M. Abumeri / KC

## Enclosures

S:\WPDATA\MMA\PACELET.SAV  
111998

## Exhibit A

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